RECORD AND BRIEFS

Supreme Court, U.S.
FILED
MAR 21 2016
OFFICE OF THE CLERK

No. 15-1039

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), *see* Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21, created a new regulatory pathway, 42 U.S.C. § 262(k), by which the FDA could approve a biologic product as "biosimilar to" a "reference product" that was itself approved under the full, traditional pathway of 42 U.S.C. § 262(a). "[B]alancing innovation and consumer interests," Pub. L. No. 111-148 § 7001(b), Congress established procedures to control and streamline patent litigation between the biosimilar applicant (the "Applicant") and the reference product sponsor (the "Sponsor" or "RPS"), *see* 42 U.S.C. § 262(*l*), triggered by the filing of an application under the new abbreviated pathway, *see id.* § 262(*l*)(1)(B)(i).

Sandoz Inc.'s petition for a writ of certiorari ("Sandoz's Petition") addresses part of those patent-litigation procedures, namely the requirement in subparagraph 262(*l*)(8)(A) that the Applicant provide 180 days' notice to the Sponsor before the first commercial marketing of the licensed biosimilar. Sandoz asks this Court to review this question:

> Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(*l*)(8)(A) as a stand-alone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

QUESTIONS PRESENTED (CONTINUED)

(Pet. at ii.)

Respondents Amgen Inc. and Amgen Manufacturing Limited (together, "Amgen") have today filed a Conditional Cross-Petition for a writ of certiorari to review an aspect of the Federal Circuit's decision that involves the same patent-dispute-resolution regime. Amgen's Cross-Petition presents this question:

> Is an Applicant required by 42 U.S.C. § 262(*l*)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant "shall provide," and, where an Applicant fails to provide that required information, is the Sponsor's sole recourse to commence a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)?

(Cross-Pet. at i-iii.)

For the reasons set forth below, the Court should deny Sandoz's Petition. If the Court does so, it should deny Amgen's Cross-Petition too. If, however, the Court grants Sandoz's Petition, it should consider both questions regarding the patent-resolution scheme of the BPCIA by granting Amgen's Conditional Cross-Petition as well.

PARTIES TO THE PROCEEDINGS

The caption identifies all parties. Petitioner is Sandoz Inc. Respondents are Amgen Inc. and Amgen Manufacturing Limited.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondents Amgen Inc. and Amgen Manufacturing Limited state the following:

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with a 10% or greater ownership in Amgen Manufacturing Limited.

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BRIEF IN OPPOSITION

The Petition fails to satisfy the criteria for a grant of certiorari and should be denied.

This case is a poor vehicle for the Court's first interpretation of the BPCIA, for three reasons: First, the only part of Sandoz's question presented that is actually presented by this record is the part that the Federal Circuit decided unanimously, correctly holding that notice of commercial marketing is effective only if given after FDA licensure of the biosimilar product. Second, the rest of Sandoz's question presented, about the existence of a private right of action and the availability of injunctive relief, is moot on these facts, and the legal issues were not presented below. And third, the issues that are not ripe here are currently being litigated in the lower courts, including in a case in which the Federal Circuit will hear oral argument on April 4, 2016. This case is not an appropriate vehicle for this Court to decide these issues.

The Timing of Notice: The first half of Sandoz's question presented addresses whether notice of commercial marketing may be given before, or is effective only if given after, FDA licensure of the biosimilar product. The Federal Circuit correctly, and unanimously, decided that notice of commercial marketing is effective only if given after FDA licensure. The words of the statute are clear:

> Notice of commercial marketing. The subsection (k) applicant shall provide notice to the reference product sponsor not later

> than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

42 U.S.C. § 262(*l*)(8)(A) (emphasis added). Congress's use of the words "the biological product licensed under subsection (k)" was deliberate. In every other place in which subsection 262(*l*) refers to the proposed biosimilar product, it uses the phrase "the biological product that is the subject of" the subsection (k) application. *See, e.g.*, 42 U.S.C. § 262(*l*)(3)(A), (B), (C), (*l*)(7)(B). Here, and here only, the statute refers to "the biological product licensed under subsection (k)." That is because notice may be given only after the FDA has licensed (that is, approved) the biological product. Sandoz offers a raft of policy arguments for why this is supposedly a bad or unfair rule, arguments that are wrong on their merits but that in any event cannot overcome the statute's text. The Federal Circuit's decision is correct and not in conflict with the statute or any of this Court's decisions. This issue is therefore not appropriate for certiorari review.

Private Right of Action and Injunctive Relief: Sandoz argues that the Federal Circuit created an improper, extra-statutory remedy for an Applicant's failure to give timely notice, improperly created a private right of action to enforce subparagraph 262(*l*)(8)(A) where an Applicant does not provide timely notice of commercial marketing, and improperly "fashioned its own injunctive remedy" for that private right of action. (*E.g.*, Pet. at 19, 32.) But Sandoz provided timely notice after FDA

approval of its application, and thus this case does not present the question of what remedies would be available if an Applicant failed to do so. Moreover, Amgen did not sue on a private right of action to enforce the BPCIA; it brought established California state-law claims. (*See* Pet. App. at 63a-64a; D. Ct. Dkt. No. 1 (alleging causes of action for unfair competition under Cal. Bus. & Prof. Code § 17200 et seq. and conversion).) The district court expressly declined to reach whether there is a private right of action under the BPCIA because Amgen's state-law claims did not raise that issue. (*See* Pet. App. at 67a n.4.) After the district court denied Amgen's motion for a preliminary injunction, Amgen sought an injunction pending appeal pursuant to Fed. R. App. P. 8(a), based on the traditional four-factor test for equitable relief, and the Federal Circuit granted Amgen's motion. (*See* CAFC Dkt. No. 55 (Amgen's motion); CAFC Dkt. No. 83 (Sandoz's opposition); CAFC Dkt. No. 105 (order granting the motion).) The court's power came from the Federal Rules.

Cases Pending in the Lower Courts: The very issues in Sandoz's question presented that are not ripe here are currently percolating in the lower courts. To date there have been only seven lawsuits involving a biosimilar applicant's submission of an abbreviated biologics license application ("aBLA") to the FDA. All are still pending, and they present questions not only of underlying patent-law issues—whether a given product infringes a given patent, and the like—but also questions about how the BPCIA patent-litigation procedures are to be construed and applied. For example, on April 4,

2016, the Federal Circuit will hear oral argument in a case that presents one of the issues Sandoz wrongly asks this Court to decide here: whether a court has the power to issue a preliminary injunction where an Applicant refuses to provide notice of commercial marketing under subparagraph 262(*l*)(8)(A). *See Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. appeal docketed Dec. 11, 2015). That case also presents another question closely related to Sandoz's question presented here: The Federal Circuit will decide whether the obligation to give notice of commercial marketing under subparagraph 262(*l*)(8)(A) applies to only an Applicant that refused to give the Sponsor a copy of its biologics license application under subparagraph 262(*l*)(2)(A), as Sandoz did here, or whether that notice requirement also applies to an Applicant that complies with subparagraph 262(*l*)(2)(A), as Apotex did there. Two other pending cases address whether the Federal Circuit's decision in this case creates or implies a private right of action, an issue presented on the record of those cases but not on the record of this one. *See Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. filed Sept. 18, 2015); *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-10698 (D. Mass. filed Mar. 6, 2015). The *Janssen* case also presents the related question of the impact of an Applicant's commencing the patent-litigation process called for by subsection 262(*l*) but then refusing to continue that process, as does another case between Amgen and Sandoz filed this month about a different proposed biosimilar product, *see Amgen Inc. v. Sandoz Inc.*, No. 16-01276 (D.N.J. filed Mar. 4, 2016).

Many of the components of the subsection 262(*l*) process are interlocking, and interpretation of one section can bear on many others. This Court should deny Sandoz's Petition and allow these issues to develop further, so that the Court's eventual review of these BPCIA provisions can be informed by the coming wave of district court and Federal Circuit decisions.

STATEMENT OF THE CASE

A. The Biologics Price Competition and Innovation Act of 2009

Sandoz's Petition suggests that the BPCIA was enacted to "create competition in the biologic pharmaceuticals market and to reduce prices." (Pet. at 2.) That tells only half of the story. Congress enacted the BPCIA in 2010 to establish "a biosimilars pathway balancing innovation and consumer interests." Pub. L. No. 111-148, § 7001(b) (emphasis added). Its goal is not just the regulation and licensure of potentially lower-cost biosimilar products, but also the protection of innovators' patent rights.

Before the BPCIA was enacted, the FDA could approve a biologics license application only under the full biologics pathway of 42 U.S.C. § 262(a), with its usual requirement of three phases of clinical trials to prove that "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). An innovator of a new biological product was assured that, even apart from whatever patent protection it might have on that product, no other company could copy that

biological product and obtain FDA approval without first undergoing the expense of the 262(a) pathway. The innovator's investment to create a clinical trial data package to support and maintain FDA licensure of the innovator's biologic product was thereby protected from use by or for the benefit of would-be competitors.

The BPCIA changed that. Congress created a new biosimilars approval pathway, codified in 42 U.S.C. § 262(k) and commonly called "the (k) pathway." It allows the FDA to approve a biologic product that is "highly similar" to a "reference product" that was itself previously approved under the traditional subsection 262(a) pathway. *See id.* § 262(i)(2), (k)(3). Thus, while innovators previously enjoyed permanent and exclusive rights to their clinical trial data and FDA license, the BPCIA advanced the public's interest in price competition in part by diminishing these innovators' rights. It allowed an Applicant to "reference" the innovator's license, and to demonstrate that its proposed product is "highly similar" to the innovator's "reference product," *id.* § 262(i)(2), (k)(3), rather than incurring the costs of generating its own clinical data to demonstrate safety and efficacy. The BPCIA has no grandfather provision that would limit its applicability to only reference products licensed after the effective date of the legislation. *See id.* § 262(k).

On the other side of the balance, Congress protected the public's interest in innovation by establishing in subsection 262(*l*), "Patents," what the Federal Circuit aptly termed a "unique and elaborate process for information exchange between

the biosimilar applicant and the [Sponsor] to resolve patent disputes." (Pet. App. at 6a.) The process begins when the Applicant files an aBLA seeking review under the subsection (k) pathway. *See* 42 U.S.C. § 262(*l*)(1)(B)(i). Then, "[n]ot later than 20 days after" the FDA notifies the Applicant that its aBLA has been accepted for review, the Applicant "shall provide to the reference product sponsor a copy of the application submitted" to the FDA "under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). Subsection 262(*l*) further provides for an information exchange between the Sponsor and the Applicant, including identifying patents that might be infringed by the making, using, selling, offering for sale, or importation into the United States of the product that is the subject of the subsection (k) application, detailed infringement and invalidity contentions regarding those patents, and a discussion of licensure under some or all of those patents and whether the Applicant will await the expiry of some or all of those patents before marketing its product. *See* 42 U.S.C. § 262(*l*)(3)(A), (B), (C). If there remain patents in dispute, the Sponsor and Applicant work together to identify which of those patents will be included in an "Immediate patent infringement action" under paragraph 262(*l*)(6). *See id.* § 262(*l*)(4), (5), (6).

The elaborate process in subsection 262(*l*) also includes the notice-of-commercial-marketing provision at issue here, subparagraph 262(*l*)(8)(A). Textually, it is unlinked to any of the other

provisions of subsection 262(*l*). It states simply that, "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." It is, however, included within paragraph 262(*l*)(8), entitled "Notice of commercial marketing and preliminary injunction." Subparagraph 262(*l*)(8)(B) then provides that "[a]fter receiving the notice under subparagraph (A) and before the date of the first commercial marketing of such biological product," the Sponsor may seek a preliminary injunction under certain patents that were not listed for inclusion in the "immediate patent infringement action" under paragraph 262(*l*)(6). Subparagraph 262(*l*)(8)(C) then requires the Applicant and the Sponsor to cooperate reasonably to expedite discovery if the Sponsor seeks a preliminary injunction under subparagraph 262(*l*)(8)(B).

As described below, the first half of Sandoz's question presented asks whether the notice of commercial marketing under subparagraph 262(*l*)(8)(A) may be given <u>before</u> FDA approval of the Applicant's subsection (k) application or whether, as the Federal Circuit unanimously held, that notice is effective only if given <u>after</u> FDA approval.

B. Factual Background

1. Sandoz's aBLA and its Initial Notice of Commercial Marketing

Amgen discovered, developed, and markets NEUPOGEN® (filgrastim), a genetically engineered biologic protein that stimulates the production of neutrophils, a type of white blood cell. (*See* Pet. App. at 4a, 57a; D. Ct. Dkt. No. 1 at ¶¶ 45-47.) NEUPOGEN® is used, for example, to protect against a condition known as neutropenia, a potentially fatal neutrophil deficiency, induced in cancer patients by chemotherapy. (D. Ct. Dkt. No. 1 at ¶¶ 45-47.) The advent of NEUPOGEN® profoundly changed the treatment of many forms of cancer by greatly reducing deaths from neutropenia.

Sandoz filed an aBLA under the subsection (k) pathway seeking FDA approval of a biosimilar filgrastim product, designating Amgen's NEUPOGEN® as the reference product. (Pet. App. at 8a.) The FDA notified Sandoz it had accepted that aBLA on July 7, 2014. (*Id.*) Later in July, Sandoz informed Amgen that it would not provide Amgen with its aBLA or manufacturing information under subparagraph 42 U.S.C. § 262(*l*)(2)(A), and—purporting to satisfy the notice requirement of subparagraph 262(*l*)(8)(A)—informed Amgen that it would begin commercial marketing immediately upon FDA licensure. (Pet. App. at 8a-9a.) Sandoz said it expected to receive an FDA license some six to twelve months later, in the first half of 2015. (Pet. App. at 8a.)

2. District Court Proceedings, FDA Approval of Sandoz's aBLA, and Sandoz's Second Notice of Commercial Marketing

In October 2014, Amgen sued Sandoz in the Northern District of California, asserting claims of conversion, unlawful competition under California Business & Professions Code § 17200 et seq., and infringement of U.S. Patent 6,162,427. (Pet. App. at 9a.) Amgen alleged that Sandoz had competed unlawfully and converted the value of Amgen's license for NEUPOGEN® by referencing that license under the BPCIA while refusing to disclose its aBLA and manufacturing information to Amgen under subparagraph 262(*l*)(2)(A) and giving improper notice of commercial marketing under subparagraph § 262(*l*)(8)(A). (*See id.*) Sandoz counterclaimed for declaratory judgments that its reading of the BPCIA was correct. (*Id.*) Amgen sought a preliminary injunction, and the parties cross-moved for judgment on Amgen's state-law claims and Sandoz's counterclaims. (*Id.* at 9a-10a.)

While the motions were pending, on March 6, 2015 the FDA approved Sandoz's aBLA, licensing Sandoz to sell its biosimilar filgrastim product under the name ZARXIO®. (*Id.* at 8a-9a.) That same day, while maintaining that its July 2014 notice of commercial marketing had been operative, Sandoz gave Amgen a "further" notice of commercial marketing under subparagraph 262(*l*)(8)(A). (*Id.*)

On March 19, 2015, the district court granted partial judgment to Sandoz, holding that (i) despite the use of the words "shall provide," the BPCIA allows an Applicant to refuse to provide its aBLA

and manufacturing information; (ii) where an Applicant refuses to provide that information, the Sponsor may not obtain injunctive relief, restitution, or damages for that refusal, and is instead limited to seeking a declaratory judgment under subparagraph § 262(*l*)(9)(C); and, (iii) the Applicant may give notice of commercial marketing under subparagraph 262(*l*)(8)(A) before FDA approval, and thus that Sandoz's July 2014 notice was timely. The district court entered judgment against Amgen on its state-law claims, and denied its motion for a preliminary injunction. (*Id.* at 10a.) Proceedings on Amgen's patent claim were stayed, and Amgen timely appealed to the Federal Circuit. (*Id.* at 11a.)

3. The Federal Circuit Decision

Amgen sought an injunction pending appeal under Fed. R. App. P. 8(a) and the traditional four factors of the equitable test for such an injunction: likelihood of success on the merits, irreparable harm, a balance of hardships favoring the movant, and the public interest. (*See* CAFC Dkt. No. 55.) Over Sandoz's opposition (*see* CAFC Dkt. No. 83), the Federal Circuit entered an injunction pending appeal on May 5, 2015, enjoining Sandoz from marketing, selling, or offering for sale its ZARXIO® product until the court resolved the appeal. (*see* CAFC Dkt. No. 105).

On July 21, 2015, the Federal Circuit issued its decision on Amgen's appeal. (*See* Pet. App. 1a-55a.) The panel comprised Judges Lourie, Newman, and Chen, with Judge Lourie writing the majority opinion, joined in various parts by Judge Newman, Judge Chen, or both. (*See id.*)

Judge Lourie, joined by Judge Chen, held that while subparagraph (*l*)(2)(A) says that the Applicant "shall provide" a copy of its aBLA and related manufacturing information to the Sponsor, that requirement is not actually mandatory, and where an Applicant refuses to provide that information the Sponsor's only recourse is to commence a patent-infringement suit under 35 U.S.C. § 271(e)(2)(C)(ii) or a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and obtain that information through discovery. (*See id.* at 12a-18a.) From this, Judge Newman dissented. (*See id.* at 32a-42a.)

Turning to the notice of commercial marketing under subparagraph 262(*l*)(8)(A), the Federal Circuit held, unanimously, that such notice is effective only if given after the FDA licenses the product under subsection (k). (*Id.* at 18a-22a.) The court based this conclusion on the language of subparagraph 262(*l*)(8)(A) itself, on Congress's use of different language in other parts of the BPCIA, and on the purpose of a post-approval 180-day notice period, which allows a "defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product" and "ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." (*Id.* at 21a.)

The Federal Circuit then considered Sandoz's argument, pressed in that court, that the "shall" language of subparagraph 262(*l*)(8)(A) is not mandatory and that an Applicant does not need to provide notice at all. Judge Lourie, joined by Judge Newman, held that an Applicant must give notice of commercial marketing under subparagraph

262(*l*)(8)(A). (Pet. App. at 23a-26a.) Deeming Sandoz's March 6, 2015 notice of commercial marketing, given after FDA approval, to have been "operative and effective," (*id.* at 23a), the majority held that "Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.,* September 2, 2015," (*id.* at 26a), and extended the injunction pending appeal to only September 2, 2015, (*id.* at 26a, 31a). Judge Chen dissented from these parts of the panel decision. (*See id.* at 42a-55a.)

Each of Sandoz and Amgen petitioned for en banc review, with Sandoz challenging aspects of the panel's decision regarding notice of commercial marketing under subparagraph 262(*l*)(8)(A) and Amgen challenging the panel's decision regarding the Applicant's obligation to give the Sponsor a copy of its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A). (*See* CAFC Dkt. Nos. 118 & 119.) Both petitions for en banc review were denied without further opinion. (Pet. App. at 85a-86a.) Amgen sought to extend the injunction pending appeal while en banc proceedings continued (CAFC Dkt. No. 124), and that application, too, was denied. (CAFC Dkt. No. 128.) Sandoz began commercial sales of its ZARXIO® product on September 3, 2015. (Pet. at 20.)

4. Proceedings in This Court

Sandoz filed a petition for a writ of certiorari, No. 15-1039, on February 16, 2016, which was docketed on February 18, 2016.

Sandoz's Petition challenges two aspects of the Federal Circuit's decision: (1) the unanimous

holding that the notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) is effective only if given after FDA approval of the biosimilar, and not before; and (2) the extension of the injunction pending appeal through September 2, 2015, which was 180 days after Sandoz's March 6, 2015 notice of commercial marketing.

For the reasons set forth herein, Amgen respectfully submits that the Court should deny Sandoz's Petition.

Concurrently with this brief in opposition, Amgen is filing a Conditional Cross-Petition, addressing the Federal Circuit's decision that the language in subparagraph 262(*l*)(2)(A) that the Applicant "shall provide" the Sponsor with a copy of its aBLA and manufacturing information is not mandatory, and that where an Applicant refuses to provide that information the Sponsor's only recourse is to commence a patent-infringement suit under 35 U.S.C. § 271(e)(2)(C)(ii) or a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and obtain that information through discovery.

If the Court denies Sandoz's Petition, it should deny Amgen's Cross-Petition as well. If the Court grants Sandoz's Petition, however, then it should grant Amgen's Cross-Petition too, and should consider the correct interpretation of the BPCIA provisions together, rather than interpreting each provision of the statute separately.

REASONS FOR DENYING THE PETITION

While this Court has not yet interpreted the BPCIA, this case is a poor vehicle for the Court to first interpret that statute. Sandoz's question presented raises two issues, only one of which is actually presented by the factual and legal record below. That portion, the first half of Sandoz's question presented, is about the timing of effective notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A). The Federal Circuit unanimously and correctly held that notice is effective only if given after FDA approval, a conclusion consistent with the statutory text and not in conflict with any decision of this Court. (*See* Pet. App. at 22a.) The rest of Sandoz's question presented addresses the existence of a private right of action and the availability of injunctive relief, issues that are moot on these facts and that are not presented by the record. Moreover, to the extent that those issues might be worthy of this Court's review at some point, they are currently being litigated in the lower courts. One of those cases might someday be an appropriate vehicle for this Court's review; this case is not such a vehicle.

I. THE FEDERAL CIRCUIT'S RESOLUTION OF THE FIRST HALF OF SANDOZ'S QUESTION PRESENTED DOES NOT CONFLICT WITH ANY DECISION OF THIS COURT OR THE STATUTORY TEXT

The first half of Sandoz's question presented is "Whether notice of commercial marketing given before FDA approval can be effective" under subparagraph 262(*l*)(8)(A). (Pet. at ii.) The Federal

Circuit answered this unanimously, holding that notice of commercial marketing is effective only if given after FDA licensure of the Applicant's product under subsection (k). (Pet. App. at 22a.) That decision was correct, was consistent with the statutory text and purpose, and does not conflict with any decision of this Court. There is no reason to grant Sandoz's Petition to hear this issue.

The Federal Circuit began its analysis, as this Court requires in "all statutory construction cases," with "the language of the statute." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002). The "first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case," *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997), with the question of ambiguity "determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole," *id.* at 341.

That is exactly what the Federal Circuit did here. It began with the text of subparagraph (*l*)(8)(A):

> Paragraph (*l*)(8)(A) provides that "[t]he subsection (k) applicant *shall* provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k).'

(Pet. App. 18a-19a (emphases in opinion).) A product is "licensed" only after the FDA approves the application. Sandoz now twice refers to

"licensed" as an "adjective," asserting that the word "just identifies the product whose commercial marketing is relevant." (Pet. at 24; *see also id.* at 6.) The words "licensed under subsection (k)" do indeed identify the product, but "licensed" is the past tense of a verb; its use signifies that the Applicant needs to give notice once the product has been licensed. It is only after the aBLA is approved that the product becomes a "product licensed under subsection (k)." "Licensed" means "[t]o whom or for which a licence has been granted; provided with a licence." 1 Oxford English Dictionary 245 (Oxford Univ. Press, Compact ed. 1971).

As the Federal Circuit concluded, consistent with *Robinson*, this is confirmed by the context in which that language is used. (*See* Pet. App. at 20a.) Subparagraph 262(*l*)(8)(A) is the only place in subsection 262(*l*) where Congress used the phrase "the biological product licensed under subsection (k)." In every other place where subsection 262(*l*) refers to the product, Congress used the words "the biological product that is the subject of" the subsection (k) application. *See* 42 U.S.C. § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B).

The Federal Circuit faithfully applied this Court's precedents that where Congress uses two different terms or phrases it is assumed to intend different meanings. (*See* Pet. App. at 20a-21a (citing *Russello v. United States*, 464 U.S. 16, 23 (1983)).) Where Congress referred to acts occurring prior to the licensure of the product, it used the phrase "the biological product that is the subject of" the

subsection (k) application. Elsewhere in the BPCIA, where Congress used phrase "product licensed" it did so in provisions unambiguously referring to products that have already been approved by the FDA. Thus, subsection 262(d) refers to the post-approval recall from the market of a "product licensed." And paragraph 262(i)(4) defines the term "reference product" to refer to the "biological product licensed under subsection (a) against which" the proposed biosimilar product is evaluated.

Given Congress's use of these phrases, the Federal Circuit correctly concluded that the use of the phrase "product licensed" in subparagraph 262(*l*)(8)(A) meant that effective notice of commercial marketing could be given only after the FDA has approved the Applicant's aBLA and there is thus a "product licensed."

That conclusion is also supported by other provisions of the BPCIA that suggest that FDA approval and commercial marketing will occur some six months apart. Thus, paragraph 262(k)(6) affords a period of market exclusivity for the first biosimilar that demonstrates "interchangeability" with respect to the reference product. *See* 42 U.S.C. § 262(k)(2)(B), (k)(4), (k)(6). During that period, the FDA may not approve the application for any other biosimilar claiming similarity to the same reference product. Paragraph 262(k)(6) provides that the exclusivity period ends with the first to occur of five events. Notable here is the fact that one of them is one year after the first commercial marketing of the interchangeable biosimilar, while another is eighteen months after the approval of that biosimilar, suggesting that first commercial

marketing will not occur on the heels of FDA approval, but rather will follow that approval by some 180 days. *Compare* 42 U.S.C. § 262(k)(6)(A), *with id.* § 262(k)(6)(C)(ii).

Further, the contrary reading Sandoz proposes—that notice of commercial marketing may be given as soon as the Applicant files its aBLA—would render other statutory provisions unworkable. For example, subparagraph 262(*l*)(9)(A) refers to a period that begins when the Applicant provides the Sponsor with a copy of its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A), which it is to do within 20 days of being notified that the FDA has accepted that application for review, and that ends when the Applicant gives the notice of commercial marketing under subparagraph 262(*l*)(8)(A). If Sandoz were correct and an Applicant could give notice of commercial marketing as soon as it files its aBLA, the period in subparagraph 262(*l*)(9)(A) would end before it even began, rendering it meaningless. As another example, subparagraph 262(*l*)(8)(B) contemplates the Sponsor moving for a preliminary injunction during the 180-day period on patents that were identified in the paragraph 262(*l*)(3) exchanges, but that were not listed for inclusion in the immediate patent-infringement action under paragraph 262(*l*)(6) or that were later identified in accordance with paragraph 262(*l*)(7). If Sandoz were correct that the notice of commercial marketing could be given as soon as an Applicant files its aBLA, the 180-day period could elapse before the patent exchanges have been completed and before the

patents referred to in subparagraph 262(*l*)(8)(B) can even be identified.

For all of these reasons, the statutory text and context of subparagraph 262(*l*)(8)(A) make clear that notice of commercial marketing may be given only after FDA approval of the subsection (k) application—that is, when the product is licensed. But the Federal Circuit also considered, as required by *Robinson*, the broader context of the statute as a whole. 519 U.S. at 340. The court noted that when an Applicant "files its aBLA, it likely does not know for certain when, or if, it will obtain FDA licensure. The FDA could request changes to the product during the review process, or it could approve some but not all sought-for uses." (Pet. App. at 21a.) The possibility of changes in the product or its uses suggests that Congress would have intended the notice of commercial marketing and its 180-day period to follow FDA approval. "Giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court." (*Id.*)

Consider the implications of Sandoz's contrary proposal. An Applicant would file its aBLA on a product that might never be approved, seeking approval for indications that it might never obtain. The Sponsor would have to seek a preliminary injunction to prevent the sale of a product which may not happen for years, or ever. The courts would face entirely unnecessary applications for injunctive relief, and presumably would deny some or all of

them as not being ripe. On the other hand, as the Federal Circuit held, requiring that notice of commercial marketing be given only after FDA approval ensures a 180-day period in which preliminary injunctions can be sought based on the actual facts that matter—*i.e.*, the right and scope of permissible manufacture, marketing, and sale, and the approved therapeutic use or uses, all of which are defined by the FDA license:

> Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product.

(*Id.*) In contrast, if the notice of commercial marketing "could be given at any time before FDA licensure, the RPS would be left to guess the scope of the approved license and when commercial marketing would actually begin." (*Id.*)

The Federal Circuit's decision is thus consistent with the text of the provision at issue and with the surrounding context and the statute as a whole. In asking this Court to review that decision, Sandoz predominantly makes policy arguments for why it would prefer a different rule. None of those is a reason to grant the writ of certiorari.

Sandoz first gamely tries a textual argument, observing that the notice of commercial marketing is to be given by "the subsection (k) *applicant*" and

arguing that once the FDA approves the application that entity is no longer an "applicant" but a license "holder." (Pet. at 25 (adding emphasis to statutory language).) But Sandoz omits that "subsection (k) applicant" is a defined term in subsection 262(*l*), defined to refer to "a person that submits an application under subsection (k)." 42 U.S.C. § 262(*l*)(1)(A). Thus, Sandoz remains the "subsection (k) applicant" even after FDA approval of ZARXIO®; it is the person that submitted the application under subsection (k). The use of that defined term in subparagraph 262(*l*)(8)(A) says nothing about the timing of the notice obligation. It identifies who must give the notice: the Applicant.

Then Sandoz argues that requiring an Applicant to give notice after approval "makes little sense" because FDA approval is a public act so the Sponsor does not need notice from the Applicant. (Pet. at 25.) Notice "after FDA approval would be superfluous." (*Id.* at 6.) That misstates the purpose of notice. The Applicant gives notice so that the Sponsor will know <u>when</u> the Applicant will commence marketing of the now-approved product, giving the Sponsor at least 180 days to seek a preliminary injunction. It cannot be presumed that commercial marketing will always follow 180 days after approval: an Applicant might delay commercial marketing after licensure to await trial on the merits of a paragraph 262(*l*)(6) patent litigation, for commercial reasons, for supply reasons, or even to wait for the expiration of a patent. If first commercial marketing is not imminent upon licensure, the BPCIA should not be

interpreted to burden the court with an unnecessary (and perhaps not ripe) application for an injunction.

Finally, Sandoz argues that requiring 180 days between approval and commercial marketing results in an extra period of "market exclusivity" for the Sponsor beyond the 12 years provided for by paragraph 262(k)(7). (Pet. at 4; *see also id.* at 27-31.) It does not. The BPCIA does not confer any market exclusivity on a Sponsor. Market exclusivity is a period during which only the original innovative product may be on the market, ensuring a lack of competition. It "prevents a competing firm from obtaining FDA approval whether or not it has generated its own safety and efficacy data." John R. Thomas, Cong. Research Serv., *The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation* 4 (Jan. 15, 2014) (internal citations omitted) [hereinafter, "Thomas, *The Role of Patents*"]. There is no market exclusivity conferred by the BPCIA. Another company is free to generate its own clinical efficacy and safety data and to pursue its own approval of the same biologic product under the traditional approval pathway of subsection 262(a) at any time. Indeed, Teva did just that, obtaining approval on August 29, 2012 of its own filgrastim product, GRANIX®, under subsection 262(a). *See* U.S. Food & Drug Admin., *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations* (Feb. 26, 2016), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm.

What the BPCIA confers is not market exclusivity, then, but twelve years of data exclusivity. "Data exclusivity protects the safety and efficacy information—often termed the 'data package'—submitted by the brand-name firm from use by generic firms. As a result, a generic firm may not rely upon that data in support of its own application for FDA marketing approval for a period of years." Thomas, *The Role of Patents* at 4. Thus, under the BPCIA, the FDA may not approve a biosimilar application under the abbreviated pathway of subsection (k) until "the date that is 12 years after the date on which the reference product was first licensed under subsection (a)." 42 U.S.C. § 262(k)(7)(A). Whereas before the BPCIA biologics innovators enjoyed permanent data exclusivity, the BPCIA reduced that period to only twelve years.

None of this has anything to do, however, with the 180-day period under subparagraph 262(*l*)(8)(A). That provision affords no "exclusivity" at all. Take, for example, the product here: filgrastim. During the 180 days after the FDA approved Sandoz's ZARXIO® product, there was already a competing filgrastim product in the market: Teva's GRANIX® product. And Apotex has announced that it filed an aBLA seeking approval of its own biosimilar filgrastim product listing Amgen's NEUPOGEN® as the reference product. *See Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. appeal docketed Dec. 11, 2015). If the FDA approves Apotex's application someday, and Apotex has to then give 180 days' notice before beginning commercial marketing, Amgen will not enjoy any exclusivity during that period. Both Teva's GRANIX® and Sandoz's

ZARXIO® will be in the market, competing with Amgen's NEUPOGEN®.

What subparagraph 262(*l*)(8)(A) affords is not exclusivity, but notice and a time during which the Sponsor can seek, and the courts can efficiently address, a preliminary injunction application. In holding that the notice called for by that subparagraph is effective only if given after FDA approval, the Federal Circuit faithfully applied this Court's statutory-interpretation precedents, faithfully applied the text of the BPCIA, and did so consistently with the statutory context. There is no reason for this Court to grant a writ of certiorari to review that decision.

II. THE SECOND HALF OF SANDOZ'S QUESTION PRESENTED IS NOT ACTUALLY PRESENTED BY THE RECORD OF THIS CASE

The second half of Sandoz's question presented is whether "'treating Section 262(*l*)(8)(A) as a standalone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper." (Pet. at ii.) Sandoz argues that the Federal Circuit "disregarded the remedies provided by the BPCIA and instead created its own extra-textual remedy to enforce its interpretation: a private right of action for an automatic injunction." (Pet. at 31.) Sandoz accuses the Federal Circuit of thus running afoul of this Court's instruction that the courts "are not free to fashion their own remedies" and of this Court's instruction that injunctions may not issue in patent cases without satisfying the traditional equitable injunctive test.

(*Id.* at 31 (*citing Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001)) and 36 (citing *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392-93 (2006)).)

None of the principles invoked by Sandoz applies to this case. The Federal Circuit did not disregard "the remedies" in the BPCIA for a failure to give notice under subparagraph 262(*l*)(8)(A); Sandoz gave notice under that provision. Its doing so moots any question of what remedies might or might not exist if had not done so. Moreover, Amgen did not sue on an implied private right of action in this case; it brought established remedies under California state-law. And the Federal Circuit did not fashion a new injunctive remedy; it granted an injunction pending appeal pursuant to Fed. R. App. P. 8(a) under the traditional test in equity. Thus, there is no reason for this Court to grant a writ of certiorari to review the second half of Sandoz's question presented, because that half is not actually presented on this record.

1. The "Remedies" Under the BPCIA. Sandoz discusses, at some length, the provisions of the BPCIA that address an Applicant's failure to provide notice of commercial marketing under subparagraph 262(*l*)(8)(A). (*See* Pet. at 34-36.) It focuses on subparagraph 262(*l*)(9)(B), which details how the limitations on actions for declaratory judgment with respect to certain patents are to be applied by the courts. Paragraph (*l*)(9) is entitled "Limitation on declaratory judgment action." Subparagraph (*l*)(9)(A) prohibits both the Applicant and the Sponsor from commencing declaratory-judgment actions until the time that the Applicant

gives notice of commercial marketing under subparagraph 262(*l*)(8)(A), after having provided a copy of its aBLA and manufacturing information in accordance with subparagraph 262(*l*)(2)(A). *See* 42 U.S.C. § 262(*l*)(9)(A). The next subparagraph, on which Sandoz focuses, continues the prohibition on declaratory judgments by the Applicant where, among other things, the Applicant "fails to complete" the action required of it by subparagraph 262(*l*)(8)(A). *See id.* § 262(*l*)(9)(B).

Sandoz now argues that a declaratory judgment under subparagraph 262(*l*)(9)(B) is the exclusive remedy available to a Sponsor where an Applicant fails to give timely notice of commercial marketing under subparagraph 262(*l*)(8)(A), and thus that the courts do not have the power to enjoin commercial marketing by an Applicant that refuses to give timely notice.

That issue is not presented on this record. Sandoz gave timely notice on the day that the FDA approved its aBLA, March 6, 2015. (Pet. App. at 8a-9a.) In doing so, it satisfied subparagraph 262(*l*)(8)(A), as the Federal Circuit held. (*See id.* at 23a.) This case thus does not raise the question of what remedies might have been available to Amgen had Sandoz not given notice. As discussed below in Point III, however, that question is presented in the case in which the Federal Circuit will hear oral argument on April 4, 2016, in which Apotex has refused to provide notice of commercial marketing. Even if this is an issue that may someday warrant this Court's review after it has been presented in and decided by the lower courts, this is not an appropriate case in which to review that issue now.

The Court should wait for a case in which the facts present the legal question.

2. Private Right of Action. Nor is this an appropriate vehicle for this Court to determine whether there is a private right of action under the BPCIA. We begin with the pleadings: Amgen sued Sandoz in relevant part under two California state-law claims, one for conversion and one for unlawful competition under California Business & Professions Code § 17200 et seq. (*See id.* at 9a.) Amgen did not assert a private right of action under the BPCIA. Indeed, when Amgen suggested at oral argument that a private right of action might also support relief, the district court found that Amgen had not brought such a claim, that the issue was "not properly raise[d]" by the motions, and "accordingly," that it "will not be addressed." (Pet. App. at 67a.)

The Federal Circuit majority discussed notice of commercial marketing in the context of Amgen's Section 17200 claim. When Amgen filed that claim in October of 2014, Sandoz had not yet received FDA approval and it was not then clear whether Sandoz would give notice of commercial marketing upon receiving that approval. (*See* Pet. App. at 8a-9a.) At that time, Sandoz was still contending that its July 2014 notice was effective. (*See id.*) Because Sandoz ultimately gave effective notice after FDA approval, the Federal Circuit majority held that Amgen's Section 17200 claim became moot:

> As indicated, under our interpretation of the BPCIA, the July 2014 notice is ineffective, and Sandoz gave the operative notice on

> March 6, 2015. Thus, as we have indicated, Sandoz may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015. And, as indicated below, we will extend the injunction pending appeal through September 2, 2015. Amgen's appeal from the dismissal of its unfair competition claim based on the alleged violation of § 262(*l*)(8)(A) is therefore moot.

(*Id.* at 27a-28a.)

As discussed further in Point III below, the existence of a private right of action under the BPCIA is being litigated in two other pending BPCIA cases. *See Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. Nov. 6, 2015); *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-10698 (D. Mass. filed Mar. 6, 2015). Indeed, Amgen has argued in the case against Hospira that there is a private right of action under the BPCIA. Whether the decision below supports such a private right of action will need to be determined in a subsequent case. On the record of this case, Amgen did not assert an implied private right of action, but proceeded instead on California state-law claims. (*See* Pet. App. at 63a-64a.)

3. Extra-Statutory Injunction. There is also no basis for this Court to review the Federal Circuit's "extra-statutory" injunction or a violation of *eBay*, because the Federal Circuit did not issue an extra-statutory injunction or violate *eBay*.

The Federal Circuit issued an injunction pending appeal under Fed. R. App. P. 8(a). Amgen sought

that injunction by showing that it was likely to succeed on the merits, that it faced irreparable harm, that the balance of hardships favored an injunction, and that an injunction was in the public interest. (*See* CAFC Dkt. No. 55.) Sandoz opposed entry of that injunction by arguing about those very factors. (*See* CAFC Dkt. No. 83.) Sandoz lost, Amgen won, and the Federal Circuit exercised the injunctive power granted it by the Federal Rules of Appellate Procedure. (*See* CAFC Dkt. No. 105.)

Then, when the Federal Circuit issued its decision, it shortened that injunction pending appeal until only September 2, 2015, which is 180 days after the notice of commercial marketing that Sandoz gave on March 6, 2015. (Pet. App. at 27a-28a.) When Sandoz gave notice on March 6th, September 3, 2015 became the soonest Sandoz could begin commercial marketing. Sandoz's counsel was clear on this point at oral argument: "Sandoz re-gave notice on the day of approval, and . . . six months from that would be September 2nd. That would be the outside date that any injunction against marketing could apply." Oral Argument at 35:41, *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1499.mp3.

Thus, the Federal Circuit "enjoined" Sandoz from doing something it had committed not to do anyway: begin commercial marketing before September 2, 2015. Sandoz has never contended—in the district court, in the Federal Circuit, or in this Court—that an Applicant may give 180 days' notice of commercial marketing but then disregard that notice and begin marketing in fewer than 180 days.

All that Sandoz was enjoined from doing, then, is what it had already promised not to do. When Amgen sought to extend the injunction beyond September 2, 2015 in connection with proceedings en banc, the Federal Circuit denied Amgen's request. (CAFC Dkt. No. 128.) Sandoz began marketing ZARXIO® on September 3, 2015. (Pet. at 20.)

Importantly, as described below in Point III, the Federal Circuit will shortly hear argument in a case that does raise the question of a court's power to issue an injunction where the Applicant refuses to provide notice of commercial marketing, the *Amgen Inc. v. Apotex Inc.* case, to be argued on April 4, 2016.

That case, or some subsequent case, might present issues worthy of this Court's review. But none of the issues inherent in the second half of Sandoz's question presented is actually presented by the record of this case, and thus this Court should deny Sandoz's request for a writ of certiorari.

III. THIS CASE IS A POOR VEHICLE FOR REVIEW NOW BECAUSE THESE ISSUES ARE STILL BEING DEVELOPED IN ACTIVE LOWER-COURT CASES

There is no dispute that the BPCIA is an important new statute, and that its proper interpretation is an issue of great importance to innovative biopharmaceutical companies, to those who would propose to make biosimilar versions of those innovators' products, and to the public. But

what matters here is not that the statute is important, but that it is new.

There have been only seven lawsuits involving a biosimilar applicant's submission of an aBLA to the FDA, with the most recent of them (also between Amgen and Sandoz) having been filed just this month. All seven lawsuits are still pending. And each raises issues about the proper interpretation of the patent-litigation provisions in subsection 262(*l*).

"Often, a denial of certiorari on a novel issue will permit the state and federal courts to 'serve as laboratories in which the issue receives further study before it is addressed by this Court.'" *Lackey v. Texas*, 514 U.S. 1045, 1047 (1995) (Stevens, J., respecting denial of certiorari) (quoting *McCray v. New York*, 461 U.S. 961, 963 (1983)). "Disagreement in the lower courts facilitates percolation—the independent evaluation of a legal issue by different courts." *California v. Carney*, 471 U.S. 386, 401 n.11 (1985) (Stevens, J., dissenting). Because the BPCIA is an "Act of Congress relating to patents," the Federal Circuit's jurisdiction is exclusive in actions arising under the BPCIA. 28 U.S.C. § 1295(a)(1). While there cannot be a split in the circuit courts here, however, there can and will be differences in decision among the district courts, and opportunities for the Federal Circuit to resolve those differences. As part of this process, other judges of the Federal Circuit, beyond the single panel that has spoken so far, will articulate their views on the interpretation of the statute.

This Court should wait to take a BPCIA case until the law has evolved further. That is

particularly true here because, as set forth above in Point I, the only issue in Sandoz's question presented that is actually presented by this case—the timing of effective notice of commercial marketing under subparagraph 262(*l*)(8)(A)—was decided by a unanimous Federal Circuit consistently with the statutory text and this Court's precedents, and because the other components of Sandoz's question presented, while not presented here, are being decided in pending lower-court cases.

Most imminently, and as alluded to above, the Federal Circuit will hear oral argument on April 4, 2016 in a case about notice of commercial marketing under subparagraph 262(*l*)(8)(A). *See Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. appeal docketed Dec. 11, 2015). There, Apotex announced that it will not provide notice even if the FDA approves its application, so Amgen sought and obtained a preliminary injunction prohibiting Apotex from commercial marketing until it (a) receives FDA approval, (b) then gives notice under subparagraph 262(*l*)(8)(A), and (c) waits at least 180 days after giving that notice. *See id.* The Federal Circuit will decide whether such an injunction is appropriate. And the Federal Circuit will consider whether the requirement to give notice of commercial marketing applies only where an Applicant (like Sandoz, but not like Apotex) refuses to give the Sponsor a copy of its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A), or whether it applies to all Applicants.

Other pending cases present the other issues Sandoz now asks this Court to reach precipitously. For example, the dispute between Janssen Biotech

and Celltrion pending in Massachusetts raises the question of the interplay between subparagraphs 262(*l*)(2)(A) and 262(*l*)(8)(A) and whether there is a private right of action to enforce the notice of commercial marketing provision in subparagraph 262(*l*)(8)(A). *See Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-10698 (D. Mass. filed Mar. 6, 2015). The parties' summary judgment motions on those issues are before the district court now. *See, e.g.*, *Janssen*, No. 15-10698 (D. Mass. Feb. 17, 2015) (Janssen's memorandum). The case between Amgen and Hospira also raises the question of whether a private right of action exists under subparagraph (*l*)(8)(A), with Amgen arguing that it does. Hospira's motion to dismiss, addressed to the existence of a private right of action, is pending. *See Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. Oct. 13, 2015). And a case between Amgen and Sandoz that was filed just this month addresses whether an Applicant, after receiving the Sponsor's list of potentially applicable patents under subparagraph 262(*l*)(3)(A) may then unilaterally terminate the process called for by subparagraphs 262(*l*)(3)(C) through (*l*)(5), provisions that all use the "shall" language in the provisions at issue here. *See Amgen Inc. v. Sandoz Inc.*, No. 16-01276 (D.N.J. filed Mar. 4, 2016).

This Court and the public would benefit from allowing these pending cases to be resolved by the lower courts. The Federal Circuit expedited proceedings in this case and issued its decision less than two months after oral argument. If it follows the same pace in, for example, the *Apotex* case, a decision would likely issue sometime in May or

June. That decision would almost certainly issue before this Court begins its October 2016 Term, and will bear directly on the issues presented here.

While that is a sufficient reason for this Court to deny Sandoz's Petition and allow further, lower-court percolation of these issues, there are other reasons too.

First, there is little factual urgency here. Unlike Abbreviated New Drug Applications under the Hatch-Waxman Act[1] of which the FDA has already approved fourteen in 2016 alone, *see* U.S. Food & Drug Admin., *ANDA (Generic) Drug Approvals*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ (last visited Mar. 21, 2016), there have been seven biosimilar applications submitted as of September 30, 2015, and the FDA thus far has approved only one aBLA under the subsection (k) pathway, Sandoz's application for ZARXIO®. *See* E. Research Grp., Inc., *Review of Biosimilar Biologic Product Applications* at ES-2 (Feb. 24, 2016), http://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM488846.pdf. Thus, while this case presents the question of whether notice of commercial marketing must follow FDA approval, this is not a circumstance in which that issue will actively bear on dozens of pending applications.

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[1] Drug and Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355, 28 U.S.C. § 2201, and 35 U.S.C. §§ 156, 271, & 282).

Second, while Sandoz's Petition frames the issue as an urgent need to put low-cost medications in the hands of prescribers and patients, the need is not urgent and the cost is not meaningfully lower. It is not urgent because thus far ZARXIO® is the only approved biosimilar in America. And Sandoz is pricing ZARXIO® at only a 15% discount from Amgen's wholesale price, a far cry from the much greater price reductions—as high as 80 to 85%—typically seen with generic drugs in the small-molecule market under the Hatch-Waxman Act. *See* Fitch: Gradual Conversion Begins as First Biosimilar Hits US Market, Business Wire, (Sept. 16, 2015), http://www.businesswire.com/news/home/20150916006137/en/Fitch-Gradual-Conversion-Begins-Biosimilar-Hits-Market#.Vfrzj526dbW; Food & Drug Admin., *Facts about Generic Drugs*, http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm (last visited Mar. 21, 2016).

The impact on consumer costs from this Court waiting for the issues to develop further in the lower courts and at the FDA would be minimal, while the benefit to the Court of further developments in the law would be significant.

CONCLUSION

For the foregoing reasons, Sandoz's Petition should be denied.

Respectfully submitted,

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MARCH 21, 2016